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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,419	10/01/2003	Hirotoshi Adachi	MUR-022-USA-P	5125

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EXAMINER	
NOLAN, JASON MICHAEL	
ART UNIT	PAPER NUMBER
1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,419	ADACHI ET AL.	
	Examiner	Art Unit	
	JASON NOLAN	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment in response to Non-Final Rejection, filed 10/22/2008. Claims 17-39 are pending in the instant application; of which, Claim 17 is currently amended and Claims 26-39 are new.

Response to Amendment

Applicant's amendments with respect to Claim 17 have been fully considered and are entered. Said amendment includes the concentration of a water swelling polymer (0.001-50.0 wt%), whereas New Claim 26 narrows the concentration to 0.01-20.0 wt%.

Response to Arguments

Applicant's arguments filed August 20, 2008 have been fully considered. Applicant states that Sun *et al.* (US 6,678,554) utilizes the polymer compositions to prevent an increase in pH of the electrode medium in the reservoir rather than maintain the pH of the electrode medium. The Examiner agrees and withdraws the 102(e)-prior art rejection of Claims 17-25. Applicant states that Iga *et al.* (US 6,322,550) does not support an anticipation rejection based on the doctrine of inherency. The Examiner agrees and withdraws the 102(e)-prior art rejection of Claims 17-25. However, the Examiner is not persuaded that the instant claims are drawn to a non-obvious invention with respect to Iga *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Obviousness under 35 U.S.C. § 103 is a question of law, but is based on underlying facts of each case. The Supreme Court stated that an invention may be found obvious if it would have been obvious to a person having ordinary skill to try a course of conduct:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR International Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

Although a combination of relevant options in a particular art may be obvious to try, there are instances where an invention would not have been obvious to try:

1) When the inventor would have had to try all possibilities in a field unreduced by direction of the prior art. In other words, when "what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful" an invention would not have been obvious. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). This is another way to express the *KSR* prong requiring the field of search to be among a "finite number of identified" solutions. 550 U.S. at 421.

2) An invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution. A finding of obviousness would not obtain where "what was 'obvious to try' was to explore a technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *O'Farrell*, 853 F.2d at 903. This expresses the same idea as the *KSR* requirement that the identified solutions be "predictable." 550 U.S. at 421.

In the instant application, Claims 17-35 are drawn to a device structure for iontophoresis comprising (a) an electrically conductive layer, and (b) an electrode for supplying electric current to (a). Claims 36-39 are drawn to a method of manufacturing such iontophoresis device structures. Iontophoresis devices have been an established technology since at least 1934. *See, i.e.*, US 1,967,927. The prosecution record of the

instant application includes US Patents 6,678,554; 6,416,503; and 6,322,550 – all of which are drawn to drug delivery technologies wherein the active ingredient is delivered transdermally via iontophoresis.

Applicants state that one problem in the art involves the pH elevation of the electrically conductive layer. Applicants state that there has been no solution identified for means to control the pH changes that occur during energizing the device with current. *See* specification p. 6, ll. 9-17. Thus, the purpose of the instant invention is to develop a composition that will enable stable drug absorption without decreasing the drug transfer rate. *Id.* at p. 6, ll. 24-27.

The Examiner finds that the scope of the instant invention is drawn to an improvement over the prior art, wherein the improvement is using a water swelling polymer composition in the electrically conductive layer. *Id.* at p. 7, ll. 2-14.

In this case, Claims 18-21, 26-30, & 32-39 are drawn to an iontophoresis device comprising a basic water swelling polymers such as aminoalkyl methacrylate copolymer E, an active ingredient, a surfactant, and methods of manufacturing said device.

In this case, Claims 22-39 are drawn to an iontophoresis device comprising an acidic water swelling polymers such as methacrylic acid copolymer L and/or copolymer S, an active ingredient, a surfactant, and methods of manufacturing said device.

Claims 17-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,322,550 in view of L. Brannon-Peppas *Medical Plastics and Biomaterials Magazine*, November 1997.

1. Determining the scope and contents of the prior art – Iga *et al.* (US 6,322,550) discloses a method for transdermal administration by iontophoresis. "Substances to control drug release include . . . aminoacrylmethacrylate copolymers (Eudragit E, Eudragit RS), methacrylic acid copolymers (Eudragit L, Eudragit S). . ." *See* col. 8, ll. 10-23. Surfactants are considered drug absorption promoters and are discussed in col. 7, ll. 40-1.

Brannon-Peppas discloses that there are three primary mechanisms by which active agents can be released from a delivery system: diffusion, degradation, and swelling followed by diffusion. *See* p. 5. For transdermal drug delivery, the penetration of the drug through the skin constitutes an additional series of diffusional and active transport steps, as shown in Figure 4 on p. 6. It is disclosed that: "To be successfully used in controlled drug delivery formulations, a material must be chemically inert and free of leachable impurities. It must also have an appropriate physical structure, with minimal undesired aging, and be readily processable." *Id* at. p. 3. A range of materials have been employed to control the release of drugs and have been selected for their desirable physical properties, shown below (*see* p. 3):

- Poly(urethanes) for elasticity.
- Poly(siloxanes) or silicones for insulating ability.
- Poly(methyl methacrylate) for physical strength and transparency.
- Poly(vinyl alcohol) for hydrophilicity and strength.
- Poly(ethylene) for toughness and lack of swelling.
- Poly(vinyl pyrrolidone) for suspension capabilities.

The reference then discloses the typical polymers used in controlled drug delivery, shown below:

- Poly(2-hydroxy ethyl methacrylate).
- Poly(N-vinyl pyrrolidone).
- Poly(methyl methacrylate).
- Poly(vinyl alcohol).
- Poly(acrylic acid).
- Polyacrylamide.
- Poly(ethylene-co-vinyl acetate).
- Poly(ethylene glycol).
- Poly(methacrylic acid).
- Polylactides (PLA).
- Polyglycolides (PGA).
- Poly(lactide-co-glycolides) (PLGA).
- Polyanhydrides.
- Polyorthoesters.

2. Ascertaining the differences between the prior art and the claims at issue – as pointed out by Applicant, Iga *et al.* does not disclose the water swelling polymer as having an average molecular weight of 100,000-1,000,000 Dalton and having a polarity selected considering the dissociation of the active ingredient for controlling pH variation.

3. Resolving the level of ordinary skill in the pertinent art – the level of ordinary skill in the art may be found by inquiring into: (1) the type of problems encountered in the art; (2) prior art solutions to those problems; (3) the rapidity with which innovations are made; (4) the sophistication of the technology; and (5) the education level of active workers in the field. *Custom Accessories, Inc.*, 807 F.2d at 962. All of those factors may not be present in every case, and one or more of them may predominate. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed.Cir.1983).

Based on the typical education level of active workers in the field of drug delivery, as well as the high degree of sophistication required to solve problems encountered in the art, the Examiner finds that a person of ordinary skill in the art would have at least a college degree in a related field, such as chemistry or biotechnology, and at least four years of work experience, i.e. a masters or doctorate level scientist.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness – The specification (pp. 13-14) states: "in such ranges, it does not affect the performance of the electrically conductive layer (such as gel property and drug release)." As such, it appears that such a broad range of concentration is not a critical limitation for the performance of the iontophoresis device structure.

Conclusion – the Federal Circuit stated "[o]bviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success." *In re O'Farrell* at 903-904. *In this case*, the prior art cited above supports the conclusion that a person of ordinary skill in the art, at the time of invention, would have been motivated to try known options within their technical grasp in the formulation art.

Iga *et al.* discloses the use of substances to control drug release including aminoacrylmethacrylate copolymers (Eudragit E, Eudragit RS) and methacrylic acid copolymers (Eudragit L, Eudragit S). This disclosure is not vague, but in fact provides guidance as to which polymers are likely to be successful. Brannon-Peppas discloses a range of materials that have been employed to control drug release, and that they are selected according to their desirable physical properties.

Thus, the references and prior art as a whole disclose a finite number of predictable solutions for a skilled artisan attempting to provide the best composition for iontophoresis. Because the specification fails to produce evidence of unexpected results, a long-felt industrial need, or other secondary considerations, the Examiner concludes that one of ordinary skill in the art would have been motivated to arrive at the instant claimed invention with an expectation of success.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan whose telephone number is (571) 272-4356 and e-mail is Jason.Nolan@uspto.gov. The examiner can normally be reached Monday - Friday (9:00AM - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^{c}Kane, may be contacted at Joseph.McKane@uspto.gov or (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, (Private PAIR or Public PAIR). Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see http://pair-direct.uspto.gov. For questions on Private PAIR system, contact the Electronic Business Center at (866) 217-9197.

/Jason M. Nolan/

Examiner, Art Unit 1626